while being very effective. Interim imaging with angiography, OCT and IVUS suggest effective inhibition of neointimal hyperplasia with a high rate of strut coverage.

TCT-250

An All Comers Randomized Trial Comparing Xience Prime and Promus Element Stents. Preliminary Results

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Background: The everolimus-eluting stents, Xience TM, has shown the best safety and efficacy profile in the trials conducted so far. Recently a new everolimus-eluting stent with a platinum based platform has been introduced in the market, the Promus Element TM. There is only one study comparing both stents but with important exclusion criteria. We have conducted a randomized all comers study aimed to compare these stents in a real practice scenario.
Methods: During a 12 months period patients undergoing revascularization and suitable for a long-term dual antiplatelet therapy were randomized to treatment with Xience Prime (XP) or Promus Element (PE) stents. A similar strategy of implantation was applied (comparable implantation pressure, predilatation, postdilatation or IVUS usage). Primary end-point is death, infarction and target lesion revascularization at 12 months.
Results: A total of 300 pts have been included, 150 treated with XP and 150 with PE. The clinical and angiographic characteristics were well balanced in both groups without significant differences. After a median follow up of 350 days (241-431) in the XP group there were 4 (2.7%) deaths, 3 cardiac (2 sudden, 1 infarction), 1 (0.7%) non-lethal infarction and 5 (3.3%) revascularizations (2 in restenosis and 3 in new lesion). There were 2 (1.3%) thrombosis, 1 definite and 1 probable, the latter corresponding to one of the sudden deaths. In the PE group there were 3 (2%) deaths (1 cardiac due to heart failure), 2 (1.3%) non-lethal infarctions and 6 (4%) revascularizations (3 in restenosis and 3 in new lesions). No thrombosis were reported. In the analysis of survival curves no significant differences were observed for the primay end-point (7 pts in XP group and 8 in PE group have reached this end-point so far).
Conclusion: The preliminary results of this all comers trial do not show significant differences between Xience Prime and Promus Element stents. A longer follow-up is required and will be reported.

TCT-251

Comparison of Polymer-Free BioFreedom™ Stents with Durable Polymer Taxus Liberté™ Stents: 2-Year Results from the BioFreedom First-In-Man Trial

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Background: Drug-eluting stents reduce the rate of TLR compared with bare metal stents. However, there is still concern of an increased incidence of very late stent thrombosis associated with 1st generation DES potentially related to the durable polymer. The BioFreedom™ stent (BFD) releases Biolimus A9™, without the use of a polymer or binder. This trial aims to demonstrate the safety and effectiveness of the BioFreedom stent as compared to the Taxus Liberté™ stent.
Methods: The BioFreedom FIM trial is a prospective, multi-center, randomized, single-blind study. In total, 182 patients were enrolled in two cohorts and randomized to BFD Standard Dose (SD, 15.6 µg/mm), or BFD Low Dose (LD, 7.8 µg/mm), or Taxus Liberté™ drug eluting stents at 4 centers in Germany. The first 75 patients received angio and IVUS FU at 4 months (1st cohort), the remaining patients (n=107) received angio and IVUS FU at 12 months (2nd cohort). The primary endpoint is in-stent Late Lumen Loss (LL) at 12 months. The secondary endpoints are IVUS neointimal volume at 4 months; MACE (death, MI, emergent Bypass or clinically-driven TLR) and ST rates (ARC defined) at 30 days, 4 and 12 months, 2, 3, 4 and 5 years.
Results: At 12 months, the clinical FU for all patients was 99% and 92% of patients had angiographic FU (2nd cohort). The in-stent LL was non inferior in BFD SD vs.Taxus: 0.17mm [0.09, 0.39] vs. 0.35mm [0.22, 0.57] Pnon-inf=0.001), with a trend towards superiority for BFD SD compared to Taxus (Psup=0.11) at 12 months. There was no significant difference in MACE (BFD SD: 6.1% vs. BFD LD: 11.6% vs. Taxus 5.5%). No stent thrombosis was seen in either BFD SD, BFD LD or Taxus. The 2-year clinical evaluation is ongoing and will be available at the time of this presentation.
Conclusion: The BioFreedom polymer-free drug coated stent had comparable efficacy in inhibiting neointimal hyperplasia vs. a currently available DES with durable polymer at 12 months in a randomized clinical trial. Both BFD SD and BFD LD demonstrated sustained safety up to 12 months, including absence of stent thrombosis. The BioFreedom FIM 2-year follow-up results will be reported for the 1st time during this presentation.

TCT-252

Proof-of-Concept Experience with the Acrobat Svelte™ Stent-on-a-Wire System in Complex Coronary Interventions. A Multicentre European Pilot Study. The "PEACE" Study

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Background: Despite established clinical and procedural benefits, direct stenting (DS) remains challenging in complex coronary lesions given the relatively bulky profile of conventional stents. Hereby, we report our preliminary experience using the Acrobat Svelte™ system - a novel stent mounted on a 0.014' fixed wire system - which may help the strategy of DS in complex coronary lesions. We thus aimed to appraise the risk-benefit balance of the Acrobat Svelte™ in a multicenter observational study.
Methods: DS with the Acrobat Svelte™ was attempted in cases of severe vessel tortuosity, angulated take off, severe calcification, or when other stents failed to cross the lesion. Primary end-point of the study was device procedural success defined as residual stenosis <30%.
Results: 34 patients (36 lesions) were enrolled. Complex features were highly prevalent, with severe vessel tortuosity in 7 (20.6 %), angulated take off in 7 (20.6%), severe calcification in 8 (23.5%), or prior other stent failure in 1 case (2.94%). In order to deliver the stent, a 5Fr diagnostic catheter was used in 3 patients (9%), a 6Fr diagnostic catheter in 1 (3%), and a 6Fr guiding catheter in the other 30 patients (88%), whereas a buddy wire was needed in 5 patients (15%). Stent crossed the lesions at first attempt in all cases. Mean stent size was 3.1±0.4 mm and mean stent length was 17.3±3.9 mm, with 1.2±0.44 stents per patient. Post-dilatation was mandatory in 4 patients (11.7%) to achieve procedural success. Baseline stenosis by QCA was 76.2±12.3% with mean minimal lumen diameter (MLD) of 0.71±0.36 mm. MLD post stenting was 3.1±0.43 mm with an acute gain 2.4±0.61. Device success was achieved in 31 patients (91.2%), with no edge dissection in any patient and a mean procedural time of 42.2±31 minutes.
Conclusion: The Acrobat Svelte™ facilitates DS either utilizing diagnostic or guiding catheters, and can be used to treat a wide range of coronary anatomies and lesions drastically reducing the need of coronary guidewires and pre-dilatation balloon catheters.

TCT-253

Long-Term Luminal Change after Drug-Eluting Stent Implantation; Serial Angiographic Follow-up Study of the ZEST Randomized Trial

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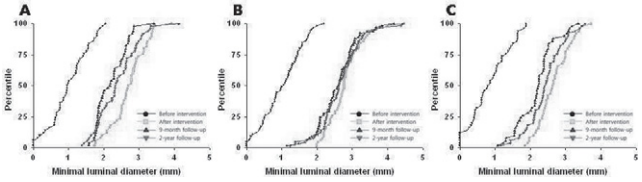
Background: Data for long-term serial change of luminal diameter after drug-eluting stents (DES) are limited. To evaluate these pattern of different DES, we analyzed serial follow-up of angiographic outcomes of zotarolimus-eluting stents (ZES), sirolimus-eluting stents (SES), and paclitaxel-eluting stents (PES) groups in the ZEST trial.
Methods: In the ZEST trial, patients were randomized to receive ZES, SES or PES in a 1:1:1 fashion. Complete after-procedure, 9-month, and 2-year angiographic data were available in 111 patients with 165 lesions (36, 40, and 35 patients, respectively).
Results: Baseline clinical, angiographic, and procedural characteristics were similar among the three groups. Quantitative angiographic analysis revealed a significant decrease in minimal luminal diameter from stent implantation to 9 months in all groups (from 2.71 ± 0.49 mm to 2.21 ± 0.42 in ZES group, p<0.001; from 2.79 ± 0.49 mm to 2.58 ± 0.57 mm in SES group, p<0.001; from 2.66 ± 0.45 mm to 2.19 ± 0.52 mm in PES group, p<0.001). However, significant late improvement in luminal diameter was observed between 9 months and 2 years in all groups with different degree of luminal change (from 2.21 ± 0.42 mm to 2.39 ± 0.58 mm in ZES group, p=0.001; from 2.58 ± 0.57 mm to 2.66 ± 0.60 mm in SES group, p=0.039; from 2.19 ± 0.52 mm to 2.43 ± 0.52 mm in PES group, p<0.001) (Figure).



Conclusion: Serial angiographic analysis for up to 2 years in the ZEST trial revealed a biphasic luminal response characterized by an early progression phase until 9 months and late regression phase from 9 months to 2 years with different degree after DES implantation.